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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/014,154
Filing Date: December 06, 2001
Appellant(s): SKIFFINGTON ET AL.

Leslie Meyer-Leon
Reg. No. 37,381
For Appellants

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 9, 2007 appealing from the Office action mailed January 31, 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

US 4,770,853	BERNSTEIN	9-1988
EP 0 309 184	SIMPSON et al.	3-1989
US 3,666,631	RICH et al.	5-1972
JP 7-59555	MATSUMOTO et al.	3-1995

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

A. Claims 1, 2, 5-7, 10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernstein (US 4,770,853) in view of Simpson et al.(EP 0 309 184) and Rich et al.(US 3,666,631).

The reference of Bernstein discloses a unit dose reagent chamber for use in a test apparatus (See Figure 4). The unit dose reagent chamber includes a cylinder with opposite open ends both of which are sealed by probe-puncturable membranes (6,7,8).

With respect to claim 1, while the reference of Bernstein discloses the use of reagent compositions within the unit dose chambers, the reference does not disclose the use of reagents specific for the detection of adenosine triphosphate wherein the reagent is either a detergent-containing buffered solution to release adenosine triphosphate from a test sample or a luciferin-luciferase reagent.

While the preferred embodiment of the reference of Bernstein is directed to the performance of an immunoassay detection, the reference discloses that the device is advantageous for assays that require multiple steps and require multiple reagents (See column 1, lines 13-28). The reference also discloses a number of types of reagents that can be used in the device including extraction reagent and lyophilized reagents (See column 3, lines 11-28).

The reference of Simpson et al. discloses a known method for the detection of adenosine triphosphate that employs a plurality of steps and reagents. The reagents include a detergent-containing buffered solution to release adenosine triphosphate from a test sample and a luciferin-luciferase reagent (See page 3, line 44, to page 4, line 15).

The reference of Rich et al. discloses that it is conventional in the art to provide reagents (92 and 94) for the detection of adenosine triphosphate in separate chambers that are separated by a frangible seal (82).

In view of these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the adenosine triphosphate detection reagents as taught by the prior art references of Simpson et al. and Rich et al. within the test device structure as disclosed by the reference of Bernstein for the known and expected result of employing an alternative means recognized in the art for storing and performing a multiple step assay while providing the benefits disclosed by the reference of Bernstein when using the disclosed reagent holding system (See column 1, lines 4-28).

With respect to claim 2, the reference of Bernstein discloses the use of aluminum foil as a probe-puncturable membrane (See column 6, line 4).

With respect to claim 5, the combination of the references as discussed above would encompass the use of a unit dose chamber (15, 20, 27) in combination with a test apparatus (13) and a detergent-containing buffered solution to release adenosine triphosphate from a test sample and a luciferin-luciferase reagent.

With respect to claim 6, the test apparatus disclosed by the reference of Bernstein includes a longitudinally moveable probe (2,5) to puncture the membrane seals.

With respect to claim 7, the closed bottom end of the apparatus (13) of the reference of Bernstein is considered a test unit that includes one or more unit dose chambers.

With respect to claim 10, whether all of the reagents are positioned within the unit dose chambers or the last employed reagent is provided in the sealed bottom, it would have been obvious to one of ordinary skill in the art for the known and expected result of providing an alternative means recognized in the art for providing reagents within a sealed chamber which are intended to be sequentially contacted with a probe member. Providing all of the reagents in a unit dose chamber would allow the tube and probe member to be manufactured independent of the specific reagents employed. However, it also would have been obvious to provide the last reagent in the sealed bottom to avoid the extra cost and materials associated with the use of an additional unit dose chamber.

With respect to claim 12, the reference of Simpson et al. discloses the additional use of a buffer or neutralizing solution (See page 3, lines 55-56) when detecting adenosine triphosphate that has been released from a cell sample using a detergent solution.

B. Claims 10, 14, 15, 17-19, 23, 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernstein (US 4,770,853) in view of Simpson et al.(EP 0 309 184) and Rich et al.(US 3,666,631) taken further in view of Matsumoto et al.(JP 7-59555).

The combination of the references of Bernstein, Simpson et al. and Rich et al. has been discussed above.

Claims 10 and 14 differ by reciting that the device includes a longitudinal housing and a separate transparent test unit attached to one end of the housing that includes the unit dose chambers.

The reference of Bernstein discloses that that lower portion or test unit (10) can be integral or separable from the housing (13) (See column 4, lines 65-68).

The reference of Matsumoto et al. discloses a known swab sample device construction that includes housing (3) and a separate test unit (1) that includes unit dose chamber (2) for separating reagents (X and 5) (See Figures 1-4).

In view of these teachings and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to provide a swab sample and reagent contacting configuration as suggested by the reference of Matsumoto et al. for the known and expected result of providing an art recognized equivalent for contacting a swab sampler with a plurality reagents.

With respect to claim 15, the reference of Bernstein discloses the use of aluminum foil as a probe-puncturable membrane (See column 6, line 4).

With respect to claim 17, the test unit (1) suggested by the disclosure of Matsumoto et al. is detachably secured to one end of the test apparatus (3).

With respect to claims 18 and 23, while the reference discloses the use of a cover (6) for the test unit, instant claim 18 differs by reciting that the test unit is sealed with a probe-puncturable membrane.

The reference of Matsumoto et al. discloses that the use of a probe-puncturable membrane (2a, 2b) is known in the art for sealing a chamber.

In view of this disclosure, it would have been obvious to one of ordinary skill in the art to seal the open end of the test unit using an additional probe-puncturable membrane in place of cover (6) for the known and expected result of providing an alternative means recognized in the art for sealing a vessel. Use of the membrane would eliminate the need to remove cover (6) since probe device (4) would be capable of penetrating the membrane sealing the test unit.

With respect to claim 19, the reference of Simpson et al. discloses the additional use of a buffer or neutralizing solution (See page 3, lines 55-56) when detecting adenosine triphosphate that has been released from a cell sample using a detergent solution.

With respect to claims 24 and 26, the reference of Rich et al. discloses providing a luciferase/luciferin reagent in tablet form (94).

(10) Response to Argument

A. With respect to the rejection of Claims 1, 2, 5-7, 10 and 12 under 35 U.S.C. 103(a) as being unpatentable over Bernstein (US 4,770,853) in view of Simpson et al.(EP 0 309 184) and Rich et al.(US 3,666,631), Appellants argue that the rejection is not proper for the following reasons (See pages 12-13 of the Appeal Brief filed 3/9/2007):

> The examiner must establish factual basis for obviousness to a preponderance of the evidence, by determining the scope and content of the prior

> art, identifying the differences between the prior art and the claimed invention as a whole, determining the level of skill in the art, and providing factual support for finding a greater than 50% likelihood that one of ordinary skill in the art would not merely have been motivated to solve the problem, but would have been motivated to arrive at the same solution as that claimed. Facts established by rebuttal evidence must be evaluated along with the facts on which the conclusion of a prima facie case was reached, not against the conclusion itself. In other words, each piece of rebuttal evidence should not be evaluated for its ability to knockdown the prima facie case. All of the competent rebuttal evidence taken as a whole should be weighed against the evidence supporting the prima facie case. In re Piasecki, 745 F.2d 1468, 1472, 223 USPQ 785,788 (Fed. Cir. 1984); MPEP 16.01(d).
>
> The examiner has not met that burden. First, the examiner has not taken all claim limitations into account, and thus has not considered the invention as a whole. Second, as demonstrated by the Second Declaration of Steven J. Saul (Exhibit A) and the Childs et al. patent (Exhibit B), it has not been established to a preponderance of the evidence that the skilled artisan would find a suggestion or motivation in the references to modify the Bernstein apparatus according to the disclosures of Simpson and Rich.

To support the above position, Appellants comments are grouped as follows: "**1. The Examiner's Rejection**" (See pages 14-15 of the Appeal Brief filed 3/9/2007); "**2. Applicant's Rebuttal Evidence**" (See pages 15-20 of the Appeal Brief filed 3/9/2007); and "**3. Taken as a whole, the evidence of record does not support a prima facie case of obviousness**" (See pages 20-26 of the Appeal Brief filed 3/9/2007).

With respect to "**1. The Examiner's Rejection**", Appellants make the following comments:

Appellants argue (See page 14, line 24, to page 15, line 6, of the Appeal Brief filed 3/9/2007) that the Examiner has misquoted Bernstein and is misleading when stating that "While the preferred embodiment of the reference of Bernstein is directed to the performance of an immunoassay detection, the reference discloses that the device is advantageous for assays that require multiple steps and require multiple reagents (See column 1, lines 13-28)". Appellants

state "Read in context, the cited passage is merely an observation as to difficulties faced in the field of point-of-care diagnostics. The passage does not make claims specific to the Bernstein device".

In response, the Examiner is of the position that one of ordinary skill in the art reading this disclosure would conclude that the device disclosed by Bernstein would be advantageous when performing assays that require multiple steps and require multiple reagents. Why else would the background section of the disclosure discuss these types of issues? One of ordinary skill in the art would clearly recognize that Bernstein is addressing a problem recognized in the art that needs to be solved. The Examiner would also like to note that while the Second Declaration of Dr. Saul (Exhibit A) goes into detail about the specifics of the preferred embodiment of the disclosed device, the declaration is silent as to how one of ordinary skill in the art would interpret the specific disclosure at column 1, lines 13-28, which is relied upon by the Examiner and argued by Appellants.

Appellants argue (See page 15, lines 7-17, of the Appeal Brief filed 3/9/2007) that the list of reagents in the reference of Bernstein discussed by the Examiner is limited to ligand-receptor assays and omits any specific suggestion of reagents useful for chemiluminescent detection of ATP.

In response, the Examiner pointed to the list of possible reagents to evidence that the reagents used in the disclosed ligand-receptor assay are similar to those employed in chemiluminescent detection of ATP. For example, the reference of Bernstein discusses the use of extraction reagents (See column 3, lines 16-26) and/or the use of detergents (See column 2, lines 19-22) in the sealed vessel (15,20). While the reference does not specifically state that the

disclosed reagents can be used in chemiluminescent detection of ATP, one of ordinary skill in the art reading the disclosure of Bernstein would have recognized that the use of extraction reagents are not limited to ligand-receptor assays, as evidence by the references of Simpson et al. and Rich.

With respect to "**2. Applicant's Rebuttal Evidence**", Appellants point to the Second Saul Declaration (Exhibit A) and Childs et al., U.S. 5,783,399 (Exhibit B) and make the following comments:

Appellants argue that the Examiner has not given proper weight to the Second Saul Declaration (Exhibit A). First, Appellants argue (See pages 16, line 23, to page 17, line 5, of the Appeal Brief filed 3/9/2007) that the Examiner has improperly applied *In re Lindell* because Dr. Saul is not an appellant or assignee with respect to the instant application and therefore does not have an interest in the outcome of the instant application as alleged by the Examiner. Second, Appellants argue (See page 17, line 6, to page 20, line 9, of the Appeal Brief filed 3/9/2007) the Examiner erred in viewing the Second Saul Declaration as being no more than declarant's opinion on the ultimate legal issue. Appellants stress that the Second Saul Declaration is not opinion evidence and includes 14 items that constitute factual evidence.

In response, *In re Lindell*, 155 USPQ 521 (CCPA 1967) was not relied upon with respect to assessing the interest of the declarant in the outcome of the case. *In re Lindell* was cited to convey to Appellants that while declarant's opinion evidence should be given some weight, it does not outweigh, in the Examiner's opinion, the teachings of the prior art references which set forth the *prima facie* case of obviousness. *Ashland Oil, Inc. v Delta Resins & Refractories, Inc.* 227 USPQ 657 (Fed. Cir. 1985) was relied upon to show that the interest of the declarant in the

outcome of the case is considered when assessing the probative value of an expert opinion. In the instant application, while the declarant is not one of the appellants or an assignee, the Examiner does not consider an employee of the assignee or coworker of the appellants a disinterested person. With respect to "Facts" 1, 3, 5, 6, 7, 8 and 9, the Examiner agrees with Appellants that these are statements of fact which any one of ordinary skill in the art would be capable of ascertaining when reading the disclosure of Bernstein. With respect to "Facts" 2, 4, 10, 11, 12, 13 and 14, the Examiner is of the position that these "Facts" are not factual evidence but rather opinion evidence. As stated previously, while opinion evidence should be given some weight, it does not outweigh the teachings of the prior art references employed in the obviousness rejections of record.

Finally, the Examiner once again would like to note that while the Second Declaration of Dr. Saul goes into detail about the specifics of the preferred embodiment of the disclosed device in the Bernstein reference, the declaration is silent as to how one of ordinary skill in the art would interpret the specific disclosure at column 1, lines 13-28 which is relied upon by the Examiner and argued by Appellants. Additionally note Appellants do not further discuss and/or argue the second piece of evidence, Childs et al. (U.S. 5,783,399) (Exhibit B) in this section of the arguments.

With respect to "**3. Taken as a whole, the evidence of record does not support a prima facie case of obviousness**", Appellants list a number of arguments with the following subgroup headings presented in the following order: "**Claims 5-7 and 10**"; "**There is no suggestion or motivation to combine the cited references**"; "**Claims 7 and 10**"; "**Claims 1, 2 and 12**"; and "**Secondary indicia of non-obviousness reduces the likelihood that one skilled**

in the art would be motivated to combine the prior art references to below the required 50% threshold".

Note the following responses to Appellants' subgroups of arguments are presented in an order different than presented by Appellants. The Examiner's responses first address the rejection as applied to claim 1 and then address the dependent claim limitations that are argued separately.

With respect to subgroup argument "**There is no suggestion or motivation to combine the cited references**", Appellants argue (See page 21, line 16, to page 23, line 17, of the Appeal Brief filed 3/9/2007) that the rejection should be withdrawn as lacking any rationale as to how or what would have suggested or motivated the skilled artisan to modify the Bernstein apparatus to provide the claimed invention. To support this position, Appellants stress that the reference of Bernstein is directed to an apparatus for performing a solid phase immunodiffusion assay and modification of the reference of Bernstein as suggested by the Examiner would have made the apparatus of Bernstein unsuitable for its intended purpose of a solid phase immunodiffusion assay. Appellants stress that the ligand receptor reaction area (10) of the device of the reference of Bernstein is incompatible with the performance of chemiluminescent detection of ATP because the area has been designed to operate independently of instrumentation such as scintillation counters, flourometers and colorimeters and because the area is not closed and any solution would leak out the hole at the bottom of the test apparatus. In view of the specific structures of the ligand receptor reaction area (10) discussed above, Appellants stress that modification of the device as proposed by the Examiner would require substantial reconstruction

and redesign of the device of Bernstein and the resulting device would then be unsatisfactory for its intended purpose.

In response, the Examiner is of the position that the prior art of record would have suggested or motivated the skilled artisan to modify the Bernstein apparatus to provide the claimed invention. First, while the preferred embodiment of the device of Bernstein is specific to immunodiffusion assays, one of ordinary skill in the art would have recognized that the disclosed teachings are capable of being adapted for other assays that require multiple steps and multiple reagents as evidenced by the disclosure of Bernstein (See column 1, lines 24-27). Note "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 216 USPQ 1038 (Fed. Cir. 1983). In this case, one of ordinary skill in the art would recognize that the reference of Bernstein is concerned with at least two separate problems, a first problem involving the performance of an assay that requires multiple steps with multiple reagents and a second problem involving visualization of an immunodiffusion assay. To address the first problem, the reference of Bernstein conveys to one of ordinary skill in the art that the combined structures shown in Figures 2, 3 and 4 allow an assay to be performed with multiple steps and multiple reagents. To address the second problem, the reference of Bernstein conveys to one of ordinary skill in the art a novel ligand receptor reaction area (10). When modifying the device as suggested by the rejection of record, the Examiner is of the position that one of ordinary skill in the art would have recognized that the ligand receptor reaction area (10) would not be required when adapting the device of Bernstein for chemiluminescent detection of ATP. As evidenced by the references of Simpson et al. and

Rich et al., one of ordinary skill in the art would have recognized that the optical visualization chamber or area (10) would merely require a sealed chamber that could be optically interrogated. The Examiner is of the position that such a modification would not require substantial reconstruction and redesign of the device of Bernstein and the resulting device would not be unsatisfactory for its intended purpose of facilitating the performance of a multiple step and multiple reagent assay since this is a problem that is addressed by the disclosure of the reference of Bernstein.

With respect to subgroup argument "**Secondary indicia of non-obviousness reduces the likelihood that one skilled in the art would be motivated to combine the prior art references to below the required 50% threshold**", Appellants argue (See page 24, line 15, to page 26, line 16) that the reference of Childs et al. (US 5,783,399) is evidence establishing secondary indicia of non-obviousness that others of ordinary skill in the relevant art arrived at alternative solutions. To support this position, Appellants reference *Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH*, 45 USPQ2d 1977 (CAFC 1998). Appellants stress that the reference of Childs et al. establishes that there is at least a 50% likelihood that one skilled in the art would have chose not to modify the Bernstein test apparatus. Appellants argue that despite having constructive possession of the cited references, when faced with the problem of using luciferin-luciferase to detect ATP on a test surface, the inventors of the Childs patent did not choose to modify the Bernstein reference but rather chose a completely different solution to that problem.

In response, the Examiner is of the position that the reference of Childs et al. fails to render the instant claims unobvious over the combination of the references of Bernstein, Simpson and Rich. The fact that the reference of Childs et al. discloses a different device for

performing a chemiluminescent detection of ATP is irrelevant in this application. Using Appellants' logic, any reference that is available as prior art and is different from an invention claimed in an application could be used to establish nonobviousness. Furthermore, it is not clear how the facts of *Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH* pertain to the instant rejection of the claims. It appears that in *Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH* the prior art references taught away from the modification proposed by the Examiner. Specifically, the problem being solved in *Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH* was hook breakage. The evidence of record established that those of ordinary skill in the art were experimenting with many different methods for reducing hook breakage and each of the references proposed a different solution. It was concluded, "this evidence creates a genuine issue as to whether those of ordinary skill would have had a motivation to combine needles with varying stem segment heights to form a trend". As a result, it is not clear how the facts presented in *Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH* are germane to the instant application. The reference of Childs et al. merely evidences that a different device is known in the art for performing chemiluminescent detection of ATP.

With respect to subgroup argument "**Claims 1, 2 and 12**", Appellants argue (See page 23, line 28, to page 24, line 14, of the Appeal Brief filed 3/9/2007) that the Examiner has not taken all claim limitations into account. Appellants support this position by emphasizing that the Examiner has not established that the reference of Bernstein discloses "a unit dose reagent chamber for use in a test apparatus for the detection of adenosine triphosphate (ATP) in a test sample" as is required of the preamble of claim 1. Appellants stress that the disclosure of the reference of Bernstein is silent with respect to the use of the device for the detection of ATP and

critical features of the device of Bernstein make it unsuitable for detection of ATP. Appellants conclude that the Examiner's reasoning that one skilled in the art would have been motivated to modify the Bernstein apparatus for any multi-step assay by placing any reagents into the vessels of Bernstein does not address the specific language of claim 1.

In response, the Examiner is of the position that all of the claim limitations of claim 1 have been taken into account and the rejection under 35 USC 103 does address the specific language of claim 1. First, the Examiner points to Figure 4 of the reference of Bernstein which discloses the cylinder and probe-puncturable membrane structures of claim 1 (See claim 1, paragraphs a) and b)). The Examiner then ascertains the differences between the prior art and the claimed invention by stating that while the reference of Bernstein discloses that a number of reagents can be contained within the chambers formed in the cylinder/membrane structure of Figure 4, the reference of Bernstein does not disclose the use of reagents specific for the detection of ATP. This statement clearly addresses the specific language of claim 1. Specifically, the reagent that is contained within the sealed compartment (See claim 1, paragraph c)) and would provide "a unit dose reagent chamber for use in a test apparatus for the detection of adenosine triphosphate (ATP) in a test sample" (See the preamble of claim 1). To address the differences and establish what is known to one of ordinary skill in the art at the time the invention was made, the Examiner points to the broad disclosure of the reference of Bernstein which discloses that "assays that require multiple steps, have multiple reagents, and have limited storage conditions are prone to misuse, especially if they are performed by individuals without adequate training or skills" (See column 1, lines 24-27). To address this problem, the reference of Bernstein provides the reagents within sealed compartments (See Figure 4) that are held

within the tube (Element 13 of Figure 3) so as to be sequentially contacted with a sample container swab (Elements 2, 5 of Figure 2). The reference of Bernstein conveys that "It is a particular object of the present invention to provide a test device that can be stored at nonrefrigerated temperatures, and can be utilized to perform an assay on a biological specimen or fluid without any additional reagents having to be provided to the test device" (See column 2, lines 61-66). The references of Simpson et al. and Rich et al. were cited by the Examiner to provide evidence that one of ordinary skill in the art recognizes that the detection of ATP involves a multiple steps and multiple reagents (See page 3, line 44, to page 4, line 15 of Simpson et al.) and that it is known in the art to provide the ATP detection reagents in separate compartments separated by a frangible seal (See Figure 3 of Rich et al.). In view of these disclosures, the Examiner concludes that one of ordinary skill in the art would be motivated to provide the reagents for the detection of ATP within a device with the construction of Bernstein for the known and expected result of providing a device that is recognized in the art for simplifying the performance of an assay that requires multiple steps and reagents while avoiding misuse and/or the adding of reagents and/or does not require refrigeration.

With respect to subgroup argument "**Claims 5-7 and 10**", Appellants argue (See page 20, line 16, to page 21, line 15, of the Appeal Brief filed 3/9/2007) that the rejection of claim 5 is improper for the same reasons as set forth with respect to claim1 and further argues that claim 5 distinguishes over the prior art because the Examiner does not address the specific language incorporated into claim 5 from claim 1.

In response, the Examiner maintains that the rejection of claim 5 is proper for the same reasons as set forth with respect to claim 1 and discussed previously above. With respect to the

specific language of claim 5, as stated in the rejection of claim 5, the combination of the references as discussed with respect to claim 1 would encompass the use of a unit dose chamber (15, 20, 27) in combination with a test apparatus (13) and a detergent-containing buffered solution to release adenosine triphosphate from a test sample and a luciferin-luciferase reagent. In view of the combined teachings of the references of Bernstein, Simpson et al. and Rich, one of ordinary skill in the art would have recognized that the detergent-containing buffered solution and luciferin-liciferase reagent would be provided separately within the test device only to be contacted as required by the assay steps specific to ATP detection.

With respect to subgroup argument "**Claims 7 and 10**", Appellants argue (See page 23, lines 18-27, of the Appeal Brief filed 3/9/2007) that the limitations of claims 7 and 10 are not obvious because the reference of Bernstein requires that the bottom end of the device be open while claims 7 and 10 require a closed bottom. Appellants reason that one of ordinary skill in the art would not provide ATP detection reagents in the device of Bernstein because the device is not closed and the reagent would leak out.

In response, first the Examiner would like to point out that while the lower portion of the reference of Bernstein includes a window or opening (11), during use, the window or opening (11) is sealed with tape (12) (See column 5, lines 16-25). As a result, the bottom end of Bernstein is closed. Additionally, as argued previously above with respect to claim 1, when modifying the device as suggested by the rejection of record, the Examiner is of the position that one of ordinary skill in the art would have recognized that the ligand receptor reaction area (10) would not be required when adapting the device of Bernstein for chemiluminescent detection of ATP. As evidenced by the references of Simpson et al. and Rich et al., one of ordinary skill in

the art would have recognized that the optical visualization chamber or area (10) would merely require a sealed chamber that is capable of being optically interrogated. The Examiner is of the position that such a modification would not require substantial reconstruction and redesign of the device of Bernstein and the resulting device would not be unsatisfactory for its intended purpose of facilitating the performance of a multiple step and multiple reagent assay since this is a problem that is addressed by the disclosure of the reference of Bernstein.

For the reasons articulated above, the Examiner is of the position that the rejection of Claims 1, 2, 5-7, 10 and 12 under 35 U.S.C. 103(a) as being unpatentable over Bernstein (US 4,770,853) in view of Simpson et al.(EP 0 309 184) and Rich et al.(US 3,666,631) is proper and should be affirmed.

B. With respect to the rejection of Claims 10, 14, 15, 17-19, 23, 24 and 26 under 35 U.S.C. 103(a) as being unpatentable over Bernstein (US 4,770,853) in view of Simpson et al.(EP 0 309 184) and Rich et al.(US 3,666,631) taken further in view of Matsumoto et al.(JP 7-59555), Appellants argue that the rejection is not proper for the following reasons:

Appellants comment (See page 27, lines 3-14, of the Appeal Brief filed 3/9/2007) that the reference of Matsumoto et al. is not directed to a separate sealed reagent chamber; to the use of multiple, aligned reagent chambers in a test unit; nor to the detection of ATP.

In response, the Examiner relied upon the reference of Matsumoto et al. to evidence that alternative configurations are recognized in the art to maintain separate reagents within a swab sample device. Note, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413,

208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Appellants also comment (See page 27, lines 15-21, of the Appeal Brief filed 3/9/2007) that the arguments set forth previously with respect to claims 1, 2, 5-7, 10 and 12 apply equally to the invention of claims 10, 14, 15, 17-19, 23, 24 and 26.

In response, the Examiner maintains that the combination of the references of Bernstein, Simpson and Rich is proper for the same reasons as set forth above with respect to the rejection of claims 1, 2, 5-7, 10 and 12.

Finally, Appellants argue that the preponderance of the evidence does not support the Examiner's conclusion of obviousness (See page 27, line 22, to page 28, line 6, of the Appeal Brief filed 3/9/2007). Specifically, Appellants argue that the reference of Childs et al. (US 5,783,399) is evidence establishing secondary indicia of non-obviousness that others of ordinary skill in the relevant art arrived at alternative solutions. To support this position, Appellants reference *Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH*, 45 USPQ2d 1977 (CAFC 1998). Appellants stress that the reference of Childs et al. establishes that there is at least a 50% likelihood that one skilled in the art would have chose not to modify the Bernstein test apparatus. Appellants argue that despite having constructive possession of the cited references, when faced with the problem of using luciferin-luciferase to detect ATP on a test surface, the inventors of the Childs patent did not choose to modify the Bernstein reference but rather chose a completely different solution to that problem.

In response, as discussed previously, the Examiner is of the position that the reference of Childs et al. fails to render the instant claims unobvious over the combination of the references

of Bernstein, Simpson and Rich. The fact that the reference of Childs et al. discloses a different device for performing a chemiluminescent detection of ATP is irrelevant in this application. Using Appellants' logic, any reference that is available as prior art and is different from an invention claimed in an application could be used to establish nonobviousness. Furthermore, it is not clear how the facts of *Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH* pertain to the instant rejection of the claims. It appears that in *Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH* the prior art references taught away from the modification proposed by the Examiner. Specifically, the problem being solved in *Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH* was hook breakage. The evidence of record established that those of ordinary skill in the art were experimenting with many different methods for reducing hook breakage and each of the references proposed a different solution. It was concluded, "this evidence creates a genuine issue as to whether those of ordinary skill would have had a motivation to combine needles with varying stem segment heights to form a trend". As a result, it is not clear how the facts presented in *Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH* are germane to the instant application. The reference of Childs et al. merely evidences that a different device is known in the art for performing chemiluminescent detection of ATP.

For the reasons articulated above, the Examiner is of the position that the rejection of Claims 10, 14, 15, 17-19, 23, 24 and 26 under 35 U.S.C. 103(a) as being unpatentable over Bernstein (US 4,770,853) in view of Simpson et al.(EP 0 309 184) and Rich et al.(US 3,666,631) taken further in view of Matsumoto et al.(JP 7-59555) is proper and should be affirmed.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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